required to invoke the jurisdiction of the federal courts. The ruling below moreover conflicts with decisions of other circuits that faithfully apply this Court's decisions. The question is also of indisputable importance. This Court has in the past granted certiorari to review important rulings of the Federal Circuit on questions of patent law, and it should do so here.[4]

This case also is an ideal vehicle to resolve the question presented. Teva's claim against Pfizer presents two distinct injuries that, in *amicus*'s submission, give rise to an Article III case or controversy. Teva is both (a) precluded from securing FDA approval, and (b) deterred from entering the market as a consequence of the prospect of patent liability. By granting the petition, the Court can efficiently address in one case whether either or both injuries are sufficient to trigger the jurisdiction of the federal courts.

Finally, it is important to recognize that the number of opportunities for this Court to resolve the question presented will diminish rapidly if certiorari is denied. The Federal Circuit's ruling precludes generic drug manufacturers from instituting litigation in the circumstances presented in this case. If this Court were to deny certiorari in this case, other similarly situated generic manufacturers would be hard-pressed to incur the costs of instituting new suits, appeal to the Federal Circuit, and petition for certiorari based merely on the prospect that in a later case the Court would reverse course and grant review.

Certiorari accordingly should be granted. At the least, the Court should invite the Solicitor General to file a brief expressing the views of the United States.

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[4] For recent examples, see, *e.g.*, *Merck KGaA* v. *Integra Lifesciences I*, 125 S. Ct. 2372 (2005), *vacating and remanding* 331 F.3d 860 (2003); *Holmes Group* v. *Vornado Air Cir. Sys.*, 535 U.S. 826 (2002), *vacating and remanding* 13 Fed. Appx. 961 (2001); *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), *vacating and remanding* 234 F.3d 558 (2000).

I. The Decision Below Is Contrary To This Court's Precedents Defining The "Case Or Controversy" Required By Article III Of The U.S. Constitution And Conflicts With The Precedent Of Other Circuits.

Congress has granted the federal courts jurisdiction to decide declaratory judgment suits brought by generic drug manufacturers against brand manufacturers to resolve patent claims to the fullest "extent consistent with the Constitution." 35 U.S.C. 271(e)(5). The Federal Circuit held that the Constitution prohibits such a suit unless the generic manufacturer "has a reasonable apprehension of [an] *imminent* suit" by the brand manufacturer. Pet. App. 16a (emphasis in original).

That ruling cannot be reconciled with this Court's precedents. "The irreducible constitutional minimum of standing,'" this Court has held, "contains three requirements":

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact" – a harm suffered by the plaintiff that is "concrete" and "actual or imminent, not 'conjectural' or 'hypothetical.'" Second, there must be causation – a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability – a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. *Citizens for a Better Env't*, 523 U.S. 83, 103 (1988) (citations omitted).

The court of appeals held that Teva failed to meet the first standing requirement because the only injury it was willing to recognize – a suit by Pfizer – was insufficiently "imminent." That holding is clearly wrong. This Court's precedents require that the *injury* be "imminent," as opposed to "conjectural" or "hypothetical." There is no requirement that *litigation* filed by the other side must be imminent. Put another way, Article III provides for jurisdiction not merely when there is a "case" but also when there is a "controversy." That requirement is satisfied in these circumstances.

The Federal Circuit's contrary holding is flatly at odds with this Court's decision in *Cardinal Chemical Co.* v. *Morton International*, 508 U.S. 83 (1993), addressing the circumstances in which Article III permits a declaratory judgment action with respect to a patent infringement claim. Recognizing that "a party seeking a declaratory judgment has the burden of establishing the existence of an actual controversy," this Court explained that "[i]n patent litigation, a party may satisfy that burden, and seek a declaratory judgment, even if the patentee has not filed an infringement action." *Id.* at 95. In support, it quoted with approval Judge Markey's recognition in *Arrowhead Industrial Water* v. *Ecolochem*, 846 F.2d 731, 734-35 (CAFC 1988), that cases such as this present

> the sad and saddening scenario that led to enactment of the Declaratory Judgment Act * * * . In the patent version of that scenario, a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword. * * * Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the *patent owner refused to grasp the nettle and sue*. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests. *The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual "controversy" required by the Act.*

Cardinal Chem., 508 U.S. at 95-96 (emphasis added). Accord 10B Charles Alan Wright et al., FEDERAL PRACTICE & PROCEDURE § 2751 (3d ed. 1988).

As this case demonstrates, the Federal Circuit refuses to heed *Cardinal Chemical*. Instead, it insists that a declaratory judgment plaintiff have not only a real and immediate contro-

versy with the defendant, but also the prospect of an imminent suit.

Outside the patent context, this Court's seminal ruling "upholding the [declaratory judgment] statute" involved, as Judge Dyk explained in his opinion dissenting from the denial of rehearing en banc, a situation precisely analogous to the one here – "one in which there was no imminent risk of suit because the potential plaintiff declined to sue." Pet. App. 61a. In *Aetna Life Insurance Co.* v. *Haworth*, 300 U.S. 227 (1937), the plaintiff insurance company sought a declaration of its obligations to the policyholders. Not only had the policyholders "not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability," *id.* at 239, but Aetna sued for the very reason that there was no present prospect of the parties' rights being adjudicated. This Court nonetheless found a sufficient controversy because the case involved a "definite and concrete dispute" relating to the parties' "legal rights and obligations." *Id.* at 242. "Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages." *Id.* at 240-41.

Prior to the transfer of exclusive jurisdiction of such questions to the Federal Circuit, the regional circuits faithfully applied this Court's precedents in analogous circumstances.[5] The Eighth and District of Columbia Circuits con-

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[5] This Court's practice of reviewing Federal Circuit decisions when "other courts have held or assumed" the contrary, *Pfaff* v. *Wells Electronics*, 525 U.S. 55, 60 (1998), recognizes that conflicts between the Federal Circuit's decisions and those of other circuits on "patent issues" are "useful in identifying questions that merit this Court's attention," *Holmes Group* v. *Vornado Air Circulation Sys.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring).

sidered not whether the plaintiff has a reasonable apprehension of an imminent suit, but instead whether the plaintiff had a reasonable apprehension that it will face either an infringement suit or *the threat of one.* See, *e.g.*, *United Christian Scientists* v. *Christian Science Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 (CADC 1987); *Sherwood Medical Indus., Inc.* v. *Deknatel, Inc.*, 512 F.2d 724, 727-28 (CA8 1975). That standard is met here, as Teva unquestionably faced a reasonable threat of suit given that Pfizer listed the '699 patent in the Orange Book, refused to provide Teva with a covenant not to sue, and sued Ivax for patent infringement.[6]

Two other circuits similarly applied a less stringent standard than the Federal Circuit's. The Ninth Circuit enquires whether "the plaintiff has a real and reasonable apprehension that he will be subject to liability" – a fact-based determination that looks at "[t]he acts of the defendant * * * in view of their likely impact on competition and the risks imposed upon the plaintiff, to determine if the threat perceived by the plaintiff [is] real and reasonable." *Chesebrough-Pond's, Inc.* v. *Faberge, Inc.*, 666 F.2d 393, 396 (1982). And while the First Circuit – which considered the question in the context of a dispute over which it had jurisdiction under World Trade Organization procedures – expressly holds that the "reasonable

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[6] In reviewing the totality of the circumstances to determine whether such a reasonable apprehension exists, the Eighth and District of Columbia Circuits have accorded weight to the fact that the patentee has previously brought infringement actions, just as Pfizer previously sued Ivax. See *Sherwood Medical*, 512 F.2d at 728 (although past infringement action, standing alone, not dispositive, patentee's entire course of conduct, including past action, gave rise to "reasonable apprehension"); *United Christian Scientists*, 829 F.2d at 1159 n.25 (noting that "prior record of infringement charges against the declaratory plaintiff or others similarly situated" is one of the factors "which courts have regularly recognized as buttressing a reasonable apprehension of impending litigation").

apprehension of suit" standard "is not the only way" to establish Article III jurisdiction unless "the only controversy surrounds a potential, future lawsuit," it holds that, even in the absence of such a potential suit, the facts of a particular case may demonstrate that such a controversy exists. See *Sallen* v. *Corinthians*, 273 F.3d 14, 25 (2001).

2. It cannot be seriously argued that Teva's declaratory judgment complaint fails to state an Article III case or controversy under this Court's precedents and the standard articulated by other circuits. There is a concrete legal controversy between Teva and Pfizer with respect to whether Teva's product infringes on Pfizer's patent. Pfizer's listing of the '699 patent in the Orange Book constituted a representation by it that "a claim of patent infringement could reasonably be asserted" against a generic equivalent on the basis of the patent. 21 U.S.C. 355(b)(1), (c)(2). Teva has alleged its intention to market a drug that, according to the Orange Book listing, Pfizer believes will violate its patent. Under the federal patent laws, Teva's filing of an ANDA challenging the validity or infringement of that patent constitutes a statutory act of patent infringement as matter of law. 35 U.S.C. 271(e)(2). Pfizer has further refused Teva's request that it acknowledge that Teva's product is non-infringing. In these circumstances, only a suit by Teva can resolve the controversy.

Nor is there any serious dispute that the current state of affairs greatly harms Teva. Even the Federal Circuit did not doubt in the *slightest* that Teva had suffered an "injury." Pet. App. 26a. Instead, it deemed the fact that "Teva is injured from a business standpoint" and "finds itself at a competitive disadvantage" (*ibid.*) irrelevant as a matter of law.

The legal dispute that Teva seeks to resolve has at least two definite, adverse consequences for Teva that would be remedied by a judgment in its favor – and, indeed, can *only* be remedied by such a judgment. First, Teva is deterred by the prospect of devastating infringement liability from entering the marketplace. Manufacturers in Teva's position frequently

have massive investments tied up in the development of their generic equivalents by the time they submit an ANDA. As Judge Mayer recognized in his dissent, ANDA applicants such as Teva "suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic product free from infringement allegations." Pet. App. 35a. "[D]eclaratory judgment actions serve an important role because the [FTC's] Generic Drug Study showed that *no* generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book." FTC Panel Br. 8 n.9 (emphasis added).

Second, even if Teva wanted to market its drug before adjudicating Pfizer's patent claim, the FDA *cannot* approve Teva's generic equivalent for at least 180 days after the expiration of Pfizer's first patent, unless Teva secures an earlier favorable patent judgment. See *supra* at 2. Thus, "[t]he controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays Teva from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against Teva." FTC En Banc Br. 9. "Absent such a decision, Teva (and every other ANDA applicant) instead must wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that Teva can advance the date of the approval of its product is through this litigation. Absent this action, Teva suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." FTC Panel Br. 21-22.

3. The Federal Circuit's holding that Teva nonetheless fails to state a justiciable controversy because it does not face an "imminent suit" from Pfizer (Pet. App. 16a) is insupportable. The "pragmatic" concern (*EMC Corp.* v. *Norand Corp.*, 89 F.3d 807, 811-12 (CAFC 1996)) that gave rise to the Federal Circuit's reasonable apprehension test is completely missing here. That requirement was adopted to "protect[]

quiescent patent owners against unwarranted litigation" when they have "done nothing but obtain a patent." *Arrowhead Indus. Water* v. *Ecolochem, Inc.*, 846 F.2d 731, 736 (CAFC 1988). The prudential standing rule thereby seeks "to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978. The rule is "but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of the law." Pet. App. 51a (Gajarsa, J., dissenting). But in this context, "exercising jurisdiction over this action does not force a lawsuit on a 'quiescent' patent-owner." FDA Panel Br. 13. To the contrary, as Judge Mayer recognized in his dissent, "[b]y listing its patent [in the Orange Book], Pfizer has informed the world that the '699 patent precludes anyone from marketing a generic sertraline hydrochloride product until it expires." Pet. App. 32a. Both the district court (*id.* 46a) and the court of appeals (*id.* 16a) recognized that Pfizer – like other brand manufacturers in its position – declined to file suit not because of ambivalence about its patent rights, but instead to prevent generic competition. Any doubt is resolved by the facts that Pfizer sued Ivax on an indistinguishable claim and refused to grant Teva a covenant not to sue.

Thus, the Federal Circuit's odd rule that litigation must be imminent before it may be brought "is ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market." FDA Panel Br. 12. The prudential interest in limiting the litigation burdens on patent holders is simply overborne in this circumstance.

In any event, even if it otherwise applied, the Federal Circuit's prudential standing rule did not survive Congress's enactment of a specific directive that the federal courts shall exercise jurisdiction over suits such as Teva to the fullest extent consistent with the Constitution. See 35 U.S.C. 271(e)(5); *Raines* v. *Byrd*, 521 U.S. 811, 820 n.3 (1997) (Congress may eliminate prudential standing rules by statute).

II. The Question Presented Is Vitally Important To Pharmaceutical Competition.

The petition for certiorari should also be granted because it presents a question of fundamental importance to competition in the pharmaceutical industry and, accordingly, to the American public that relies so heavily on lower-priced generic drugs to combat the skyrocketing costs of healthcare.

1. Because the Federal Circuit has exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic pharmaceutical companies to resolve patent disputes with brand manufacturers. The decision below provides a roadmap for brand manufacturers to preclude litigation of all such disputes. "No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent." Pet. App. 57a (Gajarsa, J., dissenting).

As this Court has previously recognized Congress enacted the statutory provisions of the Hatch-Waxman scheme at issue here "to enable new drugs to be marketed more cheaply and quickly." *Eli Lilly & Co.* v. *Medtronic*, 496 U.S. 661, 676 (1990). "Quite obviously, the purpose of [these provisions] is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." *Id.* at 678. And just as "[t]he scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement" (*ibid.*), so too it "will not work" if the patent holder can prevent generic manufacturers from establishing in court that there has been no patent infringement.

The FTC concurs that "[d]eclaratory judgment actions by ANDA applicants concerning listed patents play a vital role in the Hatch-Waxman regime" (FDA Panel Br. 12), helping to "further[] competitive pharmaceutical markets and [lower] health care costs" (FTC En Banc Br. 2). Indeed, it concludes, "even a modest delay in the entry of subsequent ANDA applicants may impose substantial costs on consumers because

competition among generic manufacturers has a strong impact on the price of a drug." FTC Panel Br. 8.

In the course of preparing this brief, *amicus* GPhA surveyed its membership to determine the significance of the question presented. The responses confirm that the Federal Circuit's decision fundamentally affects competition throughout the pharmaceutical industry. The survey conclusively established two facts: (i) the FTC and the dissenting judges below are correct in their conclusion that these circumstances present a concrete controversy; and (ii) the number of drugs affected by the ruling is large and constantly growing.

GPhA's members report that they regularly defer launching a product until they can litigate the question of patent infringement to at least a district court judgment.[7] By not bringing suit, brand companies perpetuate paralyzing uncertainty that allows them to continue selling their branded drugs

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[7] To cite just a few examples,

- Endo Pharmaceuticals launched its equivalent to Oxycontin® only after a favorable Federal Circuit ruling. *Purdue Pharma L.P.* v. *Endo Pharmaceuticals*, 410 F.3d 690 (2005).
- Eon Labs launched its equivalent to Sporanox® (produced by Johnson & Johnson affiliate Janssen) only after a favorable district court judgment. *Janssen Pharm. N.V.* v. *Eon Labs*, 374 F. Supp. 2d 263 (E.D.N.Y. 2004), aff'd, 134 Fed. Appx. 425 (CAFC 2005).
- Geneva launched its equivalent to Augmentin® only after a favorable district court judgment; other manufacturers then followed suit. *Geneva Pharm.* v. *GlaxoSmithKline*, 213 F. Supp. 2d 597 (E.D. Va. 2002), aff'd, 349 F.3d 1373 (CAFC 2003).
- Barr Labs launched its equivalent to Mircette® only after a favorable district court judgment. *Bio-Technology Gen. Corp.* v. *Duramed Pharms., Inc.*, 174 F. Supp. 2d 229, 232 (D.N.J. 2001), rev'd, 323 F.3d 1356 (CAFC 2003).
- Conversely Eon Labs has been precluded from litigating with respect to its generic equivalent to Pfizer's Accupril® and has not entered the market despite having final approval.

at monopoly prices. The decision below is particularly pernicious because it is the drugs that the public most frequently uses – and hence that give rise to the greatest possible infringement liability – that will suffer reduced competition. Infringement damages for blockbuster drugs such as Zoloft® (which generates revenues for Pfizer well in excess of $2 billion annually) would ruin most generic companies.

GPhA's members also report that the ruling below would have a sweeping effect. Generic manufacturers regularly seek to market generic equivalents and represent in their ANDAs that the patents listed in connection with the innovator drug are either invalid or will not be infringed. The most recent data published by the FDA indicates that generic manufacturers have filed such ANDA certifications for 314 drugs. See http://www.fda.gov/cder/ogd/ppiv.htm (last visited Sept. 7, 2005). More than seventy were submitted in the last two-and-a-half years alone. *Ibid.* Many of those drugs are likely to present patent issues that ought to be resolved promptly but, under the Federal Circuit's ruling, cannot.

These examples illustrate the sweep of the ruling below:

- The ruling below does not merely affect Teva even with respect to Zoloft®. Two other manufacturers filed ANDAs seeking to market generic Zoloft® products and brought similar declaratory judgment actions. Both were dismissed on the same ground as the Federal Circuit's ruling here. *Dr. Reddy's Labs.* v. *Pfizer*, No. 03-726, 2003 U.S. Dist. LEXIS 24,351 (D.N.J. July 8, 2003) (order); *Apotex* v. *Pfizer*, No. 04-CV-02539 (S.D.N.Y. Apr. 1, 2004) (order), appeal pending, No. 05-1199 (CAFC).

- The ruling below affects numerous drugs other than Zoloft®. For example, there are the attempts to litigate the patent validity/non-infringement of generic equivalents to Pfizer's Accupril® (which generates nearly $600 million in annual U.S. sales). Various generic manufacturers have filed ANDAs for Accupril®. When Pfizer failed to file suit, two of those manufacturers sought a declaratory judgment. Their

cases were dismissed, on the same rationale as the ruling below. *Mutual Pharm. Co.* v. *Pfizer*, No. 03-CV-1116, 2004 U.S. Dist. LEXIS 4846 (D.D.C. Mar. 24, 2004); *Apotex* v. *Pfizer*, No. 03-CV-990-SLR, 2004 U.S. Dist. LEXIS 11,930 (D. Del. June 28, 2004).

- Teva and Mylan Laboratories have filed ANDAs with respect to Merck & Co.'s Proscar®. Merck did not file suit against either. Mylan has a pending declaratory judgment action against Merck. *Mylan* v. *Merck & Co.*, No. 05-cv-1416 (SHR) (M.D. Pa.).

- Teva has a pending declaratory judgment with respect to SmithKline Beecham's Famvir®.

2. By substantially impeding generic competition, the Federal Circuit's ruling will directly injure consumers and the public health. Because generic drugs are generally sold for a fraction of the prices of their brand counterparts, the substitution of generic drugs for brand drugs results in billions of dollars in savings each year.[8] A one-percent increase in the substitution of generic drugs for brand drugs could result in a savings of up to $2 billion per year, while the widespread substitution of generic drugs for brand drugs whenever possible could save U.S. consumers as much as $17 billion per year. Dep't of Health and Hum. Servs. Task Force on Drug Importation, REPORT ON PRESCRIPTION DRUG IMPORTATION 68 (Dec. 2004), available at http://www.hhs.gov/importtaskforce/Report1220.pdf (visited Sept. 7, 2005); Steven Findlay, *Easy*

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[8] See FDA, FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs (June 12, 2003), available at http://www.fda.gov/oc/initiatives/generics/whitepaper.html (visited Sept. 7, 2005) (average price of a brand drug is $72, compared with $17 for its generic counterpart); Statement of the FTC on *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements*, Before the Comm. on the Judiciary of the U.S. Senate (May 24, 2001), available at http://www.ftc.gov/os/2001/05/pharmstmy.htm (estimating that consumers saved $8 to $10 billion in 1994 by substituting generics for brand drugs).

Way To Cut Costs Of Drugs: Generics, USA TODAY, May 13, 2004, at 23A.

Access to generic pharmaceuticals is thus "perhaps the single most important route to lower personal and national drug costs during the next decade." Findlay, *supra*. Indeed, the cost savings created by generic pharmaceuticals translates directly into improved public health and, thus, lives saved. As the FDA Commissioner has explained, generic drugs "are an increasingly important way to provide the American people with safe, effective and affordable medical treatment." *Generics: FDA Announces Measures To Improve Generic Drug Access*, DRUG WEEK, Mar. 26, 2004, at 231. See also Nat'l Inst. For Health Care Management, *A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace* 19 (June 2002), available at http://www.nihcm.org/GenericsPrimer.pdf (positing that "[t]he advent of [the generic equivalent of the anti-depressant Prozac]" may help rectify the "persistent under-diagnosis and under-treatment of depression in the U.S.").

The high costs of prescription are a significant – and in some cases, insuperable – barrier to proper treatment for many Americans, particularly the elderly. See *Generics Key To Cost Control*, UPI, May 19, 2005 (quoting Dr. Jan Berger, chief clinical officer of Caremark Rx Inc.: "the No. 1 reason why patients do not take their medicine is because it is too expensive"); AARP, Prescription Drug Costs And The Role Of Generic Drugs 2 (Oct. 1, 2002), available at http://assets.aarp.org/rgcenter/health/rx_generic.pdf ("[N]early one in four Americans 45 and older (24%) reported *not* being able to afford a prescription drug because no generic version was available.") (emphasis in original).

CONCLUSION

The petition for a writ of certiorari should be granted or, at a minimum, the Court should invite the Solicitor General to file a brief expressing the views of the United States.

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September 7, 2005

FILED
SEP 16 2005
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 05-48

IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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INTRODUCTION

The Federal Circuit has grafted onto Article III a limitation on the subject matter jurisdiction of federal courts in declaratory judgment actions that this Court has never articulated and that other circuits have rejected. By its ruling, the court of appeals denied jurisdiction throughout the country in a class of cases in which Congress specifically authorized declaratory judgments in order to accelerate the introduction of generic drugs and thereby moderate the explosive growth in expenditures on prescription drugs.

Pfizer's opposition to certiorari ignores this Court's settled Article III jurisprudence, the decisions of other circuits, and the importance of the questions presented for national health care policy. The petition for a writ of certiorari should be granted.

ARGUMENT

I. The Issues Presented for Review Will Continue to Affect Many ANDA Applicants Under the Medicare Amendments.

Pfizer suggests that the enactment of Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"), so altered the regulatory scheme of the Hatch-Waxman Act that the questions presented in Teva's petition will not arise in the future. Nothing could be further from the truth. If anything, the Medicare Amendments have increased the stakes.

Before the Medicare Amendments, a judgment of invalidity or noninfringement of an Orange Book patent

triggered the first ANDA filer's 180-day exclusivity period. The Medicare Amendments removed that trigger but replaced it with a provision of arguably greater consequence. Now, if the first ANDA filer does not launch its generic product within 75 days of such a judgment, the first filer forfeits its exclusivity altogether. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb), (j)(5)(D)(ii).[1] Pfizer's suggestion that the Medicare Amendments have eliminated the "concern" that led to Teva's declaratory judgment suit is, therefore, simply incorrect. That suggestion is particularly implausible because it leaves unexplained why Congress would specifically provide for a declaratory judgment remedy for generic companies *in the very amendments that, according to Pfizer, eliminated the need for the remedy.*[2]

Moreover, as Congress recognized,[3] there are various circumstances in which the owner of a patent listed in the Orange Book would choose not to commence litigation against a generic company in furtherance of a strategy to delay generic competition. For example, it is very common for companies to list multiple patents in the Orange Book

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1 While only a judgment obtained by a subsequent applicant with "tentative approval" can result in a forfeiture, such approval is commonly given if the drug described in the ANDA is found to satisfy the bioequivalency and other statutory requirements for generic drugs set forth in 21 U.S.C. § 355(j)(2)(A).

2 Indeed, one searches Pfizer's opposition (and the decision below) in vain for any explanation at all why Congress would go to the trouble of amending the Hatch-Waxman Act specifically to authorize declaratory judgment actions if, as Pfizer contends, Congress simply intended to maintain the legal status quo.

3 *See* Pet. at 16-17; Pet. App. at 77a.

with respect to a given drug.[4] A patentee might well sue a generic company on only one patent, obtain the 30 month stay of FDA approval, and hold the other patents in reserve to commence later litigation if the generic company prevails in the first suit. Such a strategy makes sense even with only one ANDA filer. The generic drug company can only obtain "patent certainty," as Congress intended to encourage the prompt introduction of generic drugs, by seeking a declaratory judgment on those other patents. Under the Federal Circuit's decision here, however, if the patentee has taken no steps beyond listing the patents in the Orange Book, the declaratory judgment action is likely to be dismissed.

Further, as the amicus briefs of the Generic Pharmaceutical Association and Apotex, Inc. make clear, the risk of catastrophic damages for launching a generic version of a blockbuster drug such as Pfizer's Zoloft® that generates hundreds of millions of dollars of sales *each month* is more than many generic companies can dare to run. The practical need to obtain patent certainty before launching is compelling, affects many companies, and *continues to exist even after the first ANDA filer's exclusivity period has run.*[5]

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[4] A search of the Orange Book for drugs for which Pfizer holds the NDA shows that Pfizer maintains multiple patent listings for a great many of its drugs. The Orange Book search page is located at http://www.fda.gov/cder/ob/docs/queryah.htm.

[5] Pfizer points to an earlier version of the Medicare Amendments that would have deemed an Orange Book patentee's failure to commence an infringement suit to "establish an actual controversy... sufficient to confer subject matter jurisdiction." Opp. at 27. But Congress rejected this version, not because it sought to preserve the "reasonable apprehension" test, as Pfizer argues, but rather because the Justice Department advised Congress that the attempt to define an "actual controversy" would usurp the power of the courts to determine the scope of Article III. *See* Brief of United States

(*continued next page*)

The issues raised by the petition are not "narrow, fact-based" issues unsuited for certiorari review. While the application of the Federal Circuit's "reasonable apprehension of imminent litigation" test may at times turn on the particular facts, whether that test is, as the Federal Circuit ruled, mandated by Article III is a pure question of law.

Pfizer also contends that Teva's announced agreement to acquire the stock of IVAX diminishes the importance of this case. As the press release that Pfizer cites[6] notes, this transaction is contingent on a number of factors, including regulatory and shareholder approval which have not yet occurred.

II. Teva's Claim for Declaratory Relief Was Ripe.

Pfizer tries to cast the decision below as an application of settled ripeness principles. Neither the Federal Circuit nor Pfizer ever characterized the issue here in ripeness terms or invoked this Court's ripeness cases in support of the denial of subject matter jurisdiction. This is not surprising because, under this Court's ripeness jurisprudence, Teva's claim for declaratory relief was plainly ripe.

The most obvious reason why that is so is that Teva seeks to resolve a patent infringement claim that has already accrued. By statute, Teva's submission of an ANDA with a

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Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer as *Amici Curiae* in Support of Petition of Teva Pharmaceuticals USA, Inc. for Rehearing *En Banc*, No. 04-1186 (Fed. Cir.). The bill as enacted preserved the proper sphere of judicial authority by creating a cause of action and directing courts to exercise jurisdiction unless it would violate Article III to do so.

[6] http://www.tevapharm.com/pr/2005/pr_536.asp

"Paragraph IV" certification that Pfizer's patent is either invalid or not infringed by Teva's generic formulation constitutes an act of infringement. 35 U.S.C. § 271(e)(2). As this Court has recognized, the purpose of this statute is precisely to create an actual controversy sufficient to support judicial resolution of disputes concerning the application of Orange Book patents to proposed generic drugs. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

Pfizer cannot deny that an infringement claim in response to a generic company's submission of an ANDA with a Paragraph IV certification would be ripe. Pfizer has commenced such actions many times, including one against IVAX on the very patent at issue here. But if Pfizer could have asserted a ripe claim for patent infringement against Teva, then it cannot dispute the ripeness of Teva's declaratory judgment action to resolve the identical claim. "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the [justiciability] inquiry is the same in either case." *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). If Teva's claim is unripe, then so is the infringement claim authorized by 35 U.S.C. § 271(e)(2), without which, as this Court observed, the Hatch-Waxman Act scheme "will not work." *Eli Lilly*, 496 U.S. at 678.

Moreover, unlike the claims in cases such as *Texas v. United States*, 523 U.S. 296, 300 (1998), Teva's claim does not "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Teva's submission of an ANDA with a paragraph IV certification constitutes a statutory act of infringing Pfizer's patent. The patent's validity depends on facts antedating its issuance, and resolution of the infringement claim turns on applying the

claims in that patent to a drug product that Teva has already developed, manufactured and described in great detail in its ANDA. There is absolutely nothing contingent or hypothetical about the claim that Teva seeks to resolve. This is not a case in which "the courts would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n, Inc.* v. *Sierra Club*, 523 U. S. 726, 733 (1998).

Nor is Teva seeking to challenge a statute that may never be enforced or whose enforcement is committed to other branches of government. *Cf. Boyle v. Landry*, 401 U.S. 77, 80-81 (1971) (declining to enjoin enforcement of criminal statutes at the behest of individuals who have never even been threatened with prosecution; companion case to *Younger v. Harris*, 401 U.S. 37 (1971)).[7] Congress specifically bestowed sole responsibility on federal courts to hear declaratory judgment actions brought by ANDA applicants under the circumstances presented here.

Finally, under this Court's formulation of the ordinary test for ripeness — which Pfizer does not even mention — there is no question that Teva's declaratory judgment action is ripe. The ripeness inquiry requires courts "to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149

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[7] Pfizer's suggestion that "[t]he Federal Circuit's 'reasonable apprehension' test is a well-established application of the imminent threat of prosecution standard," Opp. at 17, is far wide of the mark. The federalism concerns that underlie cases such as *Boyle* are immaterial here. Nor is there any administrative action with which resolution of Teva's lawsuit will interfere. On the contrary, under the Hatch-Waxman Act, the timing of FDA action depends on judicial resolution of patent disputes.

(1967). The infringement and validity issues raised in Teva's complaint are plainly fit for judicial resolution. There is no further factual development needed to resolve them and there is nothing hypothetical about them. Moreover, there is no question that Teva faces hardship if these issues are not resolved. The court of appeals so held, Pet. App. at 25a-26a, and Pfizer has not disputed the point.

III. The Ruling of the Federal Circuit Conflicts With the Rulings of This Court and Other Circuits.

Pfizer fails to reconcile the Federal Circuit's "reasonable apprehension of imminent litigation" requirement with the decisions of this Court and those of other circuits. For example, Pfizer argues that the declaratory judgment defendants in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 687 (1937), had placed Aetna on notice of an adverse legal position by claiming disability benefits in 1930 and 1931. But the insurance company brought its declaratory judgment action in 1934 and this Court's opinion never suggests that the defendants were on the verge of suing to enforce a legal position staked out several *years* before. This Court found the controversy to be justiciable because the issues were, as they are here, focused and concrete, and a decision on them would conclusively resolve an existing legal dispute.

Pfizer dismisses the decisions of this Court defining Article III's "constitutional minimum" in terms of injury in fact attributable to the defendant's conduct and redressable by the relief requested as involving "standing," and not "ripeness." As demonstrated above, shifting the focus to ripeness does not help Pfizer. Moreover, this Court has distinguished between the constitutional and prudential dimensions of ripeness, and the constitutional core of

ripeness is essentially the same as it is for standing. *See Duke Power Co. v. Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 79-81 (1978); *National Treasury Employees Union v. United States*, 101 F.3d 1423, 1427-28 (D.C. Cir. 1996). Where, as here, Congress has specifically directed federal courts to exercise subject matter jurisdiction to the constitutional limit, prudential restrictions on subject matter jurisdiction cannot affect the result.

Pfizer's attempts to explain away the other circuit court decisions that reject the Federal Circuit's "reasonable apprehension of imminent suit" requirement are not persuasive. Pfizer does not dispute that in *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), the court did not require the plaintiff to prove that he faced a reasonable apprehension of suit. *Id.* at 25. Pfizer says that *Sallen* is different because earlier consideration of the parties' trademark dispute by a private body had made the contours of that "controversy" "certain." But the contours of the dispute between Teva and Pfizer are no less certain than they were in *Sallen*: the issue is whether Pfizer's patent is valid and whether Teva's generic sertraline product infringes.

Similarly, Pfizer does not dispute that the Sixth Circuit in *Sankyo Corp. v. Nakamura Trading Corp.*, 2005 U.S. App. LEXIS 4339 (6th Cir. Mar. 15, 2005), held that the reasonable apprehension of litigation test is not constitutionally mandated. Pfizer argues that *Sankyo* applied an even more restrictive test, declining jurisdiction notwithstanding an actual threat of litigation by the defendant. However, the plaintiff in *Sankyo* did not seek to resolve the claim that was the subject of the threat but rather a dispute concerning whether that claim was subject to arbitration. The court understandably declined to resolve *that* dispute before the defendant actually carried through on